

Exhibit C

11:37:18 1 This is what the judge will or has instructed you as
2 far as the risk/benefit test. You have to balance the
3 inherent risk of harm against the utility or benefits of the
4 product design.

11:37:38 5 And you also have to determine whether Bard exercised
6 reasonable care in choosing the design for a product.

7 Ladies and gentlemen, I would submit to you that the
8 most powerful evidence on this issue, whether these designs,
9 or this design, was defective, comes straight from the words
11:38:04 10 of the FDA.

11 I urge you if there's any question in your mind to
12 look at Exhibit 5877 when you get back to the jury room.

13 5877 is the memo written by an FDA official. In
14 1996, when the agency was deciding whether to down classify
11:38:29 15 filters from Class III to Class II, and the agency determined
16 that they were going to down classify these filters despite
17 the fact that there were clearly risks associated with them.

18 And they recognized that the complications or risks
19 were potentially life-threatening, but that the disease these
11:39:01 20 filters is supposed to treat, pulmonary embolism, is also
21 life-threatening. And even aware of the very risks that the
22 plaintiff's attorney is complaining about in this courtroom,
23 even aware that those risks will occur, the FDA determined
24 that it was not an unreasonable risk of illness and injury
11:39:28 25 because of the benefits of these devices. And the agency made

11:39:31 1 that risk/benefit calculation even knowing that migration
2 could occur and reporting that migration with these devices
3 could occur between 6 and 53 percent of the time.

4 Also noting, as all the evidence has indicated here,
11:39:52 5 that minor filter migration is commonly reported and does not
6 appear to be associated with clinically significant events.

7 In other words, the agency decided to down classify
8 these filters even knowing there was this significant risk of
9 migration. And also knowing that there was a significant risk
11:40:16 10 of fracture.

11 The FDA noted that fracture is usually asymptomatic
12 and requires no treatment. And noted that the incidents of
13 fracture had been reported as 2 percent in the literature.

14 And despite knowing that that risk of fracture was
11:40:40 15 there, the agency determined that the benefits of these
16 devices was sufficiently great and outweighed those risks so
17 that the agency down classified the device.

18 And the FDA maintains that view.

19 We showed you that as recently as 2010, the FDA
11:41:00 20 issued a public health notice, directed to doctors, talking
21 about the fact that people with retrievable filters need to be
22 monitored to see whether the device is ready to be removed.
23 And in that notification, once again, 14 years after the down
24 classification, the agency recognized that there are long-term
11:41:27 25 risks associated with these devices. And those risks include

11:41:32 1 the very same things complained about by the plaintiff here.
2 The risk of filter migration, fracture, et cetera.

3 Why is the FDA willing to accept these risks for
4 these devices, including the Eclipse device? It's because
11:41:53 5 deep vein thrombosis and pulmonary embolism, as we all know
6 and as we've all heard repeatedly over these three weeks, they
7 kill people.

8 Estimates are that as many as 200,000 people a year
9 die. And people like Mrs. Jones are particularly at risk of
11:42:16 10 this near possibly fatal event when they have had a recent
11 deep vein thrombosis, as she had had when she received the
12 filter.

13 And in this exhibit, which was introduced yesterday,
14 the surgeon general noted not only is this condition a
11:42:34 15 potentially fatal condition that kills more people in this
16 country than -- each year than breast cancer, AIDS, and other
17 such things combined, but they also noted that IVC filters are
18 a viable option for the treatment of this potentially fatal
19 decision.

11:42:54 20 There is other evidence, ladies and gentlemen, as to
21 the adequacy of the design of this filter and Bard's
22 reasonableness in choosing that design. We stacked up --
23 electronically speaking, stacked up the tests. There are
24 tests -- there is test after test after test after test
11:43:17 25 conducted first with the Recovery filter.